

JUL 11 2003

K031417

Original 510(k) Premarket Notification
ILT Safe-Cross® .035" Support Catheter

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER INFORMATION

- A. Company Name: IntraLuminal Therapeutics, Inc
- B. Company Address: 6354 Corte del Abeto
Suite A
Carlsbad, CA 92009
- C. Company Phone: (760) 918-1820
- D. Company Facsimile: (760) 918-1823
- E. Contact Person: Pamela Misajon
Vice President of Regulatory Affairs and
Quality Assurance

DEVICE IDENTIFICATION

- A. Trade Name: ILT Safe-Cross® .035" Support Catheter
- B. Catalog Number: C135SN1
- C. Common Name: Support Catheter
- D. Classification Name: Percutaneous Catheter
- E. Device Class: Class II (per 21 CFR 870.1250)

IDENTIFICATION OF PREDICATE DEVICE

The ILT Safe-Cross® .035" Support Catheter is similar in design, materials, mode of operation and intended use to the Spectranetics .035 Support Catheter cleared under 510(k) K022138 and the IntraLuminal Therapeutics, Inc. ILT Safe-Cross® Support Catheter cleared under 510(k) K030984.

DEVICE DESCRIPTION

The ILT Safe-Cross® .035" Support Catheter is a single-lumen intravascular catheter coated with a Biocoat Hydak® hydrophilic coating intended for percutaneous use. It is designed to be used in conjunction with steerable wires to gain access to locations within the cardiovascular system that are remote from the site of insertion. Once accessed, guide wires may be exchanged within the catheter. The Safe-Cross® .035" Support Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

The effective length of the ILT Safe-Cross® .035" Support Catheter is a nominal 135 cm. The nominal maximum outside diameter is 4.4 French (0.057"). The I.D. at the tip of the ILT Safe-Cross® .035" Support Catheter is a nominal 0.041" and the inside diameter will accommodate commercially available 0.035" guide wires.

The ILT Safe-Cross® .035" Support Catheter is packaged in a Tyvek® covered tray that is heat-sealed to form a sterile barrier. The packaged units are sterilized with ethylene oxide gas. The device is provided "STERILE", "Non-Pyrogenic" and is intended for single use only.

INTENDED USE

The ILT Safe-Cross® .035" Support Catheter is indicated for use with a guide wire in order to access discreet regions of the vasculature. Once the region has been accessed, an exchange of one guide wire for another can occur. The Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

TECHNOLOGICAL CHARACTERISTICS

The ILT Safe-Cross® .035" Support Catheter is similar in basic materials, design, construction and mechanical performance to the predicate device.

BIOCOMPATIBILITY AND PERFORMANCE DATA

Biocompatibility testing and *in vivo* bench studies were conducted to evaluate the biological and performance characteristics of the ILT Safe-Cross® .035" Support Catheter. Biocompatibility test results indicate that the device materials are biocompatible. Performance test results indicate that the device satisfies functional performance requirements when used as indicated.

CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that the ILT Safe-Cross® .035" Support Catheter is substantially equivalent to the predicate devices and is capable of safely and accurately performing the stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2003

Intraluminal Therapeutics
c/o Ms. Pamela Misajon
6354 Corte Del Abeto, Suite A
Carlsbad, CA 92009

Re: K031417

ILT Safe-Cross .035" Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter.
Regulatory Class: Class II
Product Code: DQY
Dated: May 2, 2003
Received: June 27, 2003

Dear Ms. Misajon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

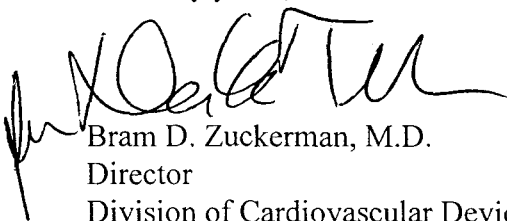
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over the typed name and title.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031417

INDICATIONS FOR USE

510(k) Number:

Device Name: ILT Safe-Cross® .035" Support Catheter

Indications for Use: The Safe-Cross® .035" Support Catheter is indicated for use with a guide wire in order to access discreet regions of the vasculature. Once the region has been accessed, an exchange of one guide wire for another can occur. The Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031417